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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/033,129	CHOO ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *42-74* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/793,408* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821(d). The application refers to sequences without the use of the correct identifier.

For example, Figures 2 and 12 each recite three different sequences, but the figures recite only one identifier for each.

Applicants should carefully review the specification to identify and properly label each sequence that is referred to within the specification, including drawings. Sequences in drawings can be identified with a SEQ ID NO: in the Brief Description of the Drawings for the figure or be present in the figure itself. If one or more sequences are referred to in the specification that are not present in the Sequence Listing, then a new Sequence Listing, a new CRF diskette containing the Sequence Listing and a new statement that the two are the same and includes no new matter must be submitted in order to fully comply with the Sequence Rules.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. Any response to this Office Action which fails to meet all of these requirements will be considered non-responsive. The nature of

the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Election/Restrictions

Newly submitted claims 42-74 are directed to inventions that are independent or distinct from the invention originally claimed (in the parent patent, Patent No. 6,007,988) for the following reasons:

I. Claims 1-41 (the originally claimed invention in the parent patent of the instant reissue application), drawn to a library of DNA sequences encoding polypeptides comprising a designed zinc finger polypeptide, method for designing a zinc finger polypeptide, method of producing a zinc finger polypeptide, and a method of modifying a nucleic acid sequence of interest present in a sample mixture, classified in class 536, subclass 23.1 and class 435, subclasses 6 and 69.1.

II. Claims 42-49, drawn to a polypeptide comprising a designed zinc finger polypeptide and at least one

functional domain, classified in class 530, subclass 350.

III. Claims 50-53, drawn to a polynucleotide encoding a polypeptide comprising a designed zinc finger polypeptide and at least one functional domain, classified in class 536, subclass 23.4.

IV. Claims 54-74, drawn to a method of altering expression of a chromosomal gene comprising contacting a target site in the gene with a designed zinc finger protein, classified in class 435, subclass 375.

The inventions are distinct, each from claims 1-41, the originally claimed invention in the parent patent of the instant reissue application, because of the following reasons:

Inventions of Group I (DNA libraries) and Group II are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The DNA libraries of Group I are not required to produce the polypeptides of Group II (the polypeptides can be produced synthetically de novo, for example) and the polypeptides of Group II are not required to produce the DNA libraries of Group I (which can be produced synthetically de novo, for example). Therefore, the inventions of the two groups are capable of supporting separate patents.

Inventions of Group I (methods) and Group II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product, a designed zinc finger polypeptide not containing at least one functional domain, and the product as claimed can be made by a materially different process, by non-selective design (e.g., molecular modeling) and expression of the designed sequence.

Inventions of Group I (DNA libraries) and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the zinc finger polypeptides encoded by the DNA sequences of the DNA libraries of Group I do not require the limitation of also comprising a functional domain, which is a

particular of the polypeptide encoded by the polynucleotide of Group III. The subcombination has separate utility such as being useful for altering the expression of a particular target site in a chromosomal gene, which is different from the utility of being the source of DNAs to be screened for the ability to bind a particular target sequence.

Inventions of Group I (methods) and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make a materially different product, a polynucleotide encoding a designed zinc finger polypeptide not containing at least one functional domain, and the product as claimed can be made by a materially different process, by non-selective design (e.g., molecular modeling) and assembly of the designed sequence.

Inventions of Group I (DNA libraries) and Group IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The DNA libraries of Group I are not used in the methods of Group IV.

The operation, function and effects of the DNA libraries of Group I (i.e. to screen for DNAs that encode a zinc finger polypeptide that binds to a particular target) are completely different and distinct from the operation, function and effects of the methods of Group IV which modulates expression of a particular gene. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups I (methods) and IV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I and IV comprise steps which are not required for or present in the methods of the other group: comparing the binding to one or more DNA triplets or selecting binding (Group I) and contacting a target site in the chromosomal gene with a designed zinc finger protein, thereby altering expression of the chromosomal gene (Group IV). The end result of the methods are different: a designed zinc finger polypeptide or a modified nucleic acid sequence of interest (Group I) and altered expression of a chromosomal gene (Group IV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Groups II-IV are not required for Group I, because each of Groups II-IV would require a different search of the non-patent literature as compared to the search of Group I because Groups II-IV are drawn to products and methods having limitations not in common with the products and methods of Group I (such as further comprising a functional domain), restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention (claims 1-41, the originally claimed invention in the parent patent of the instant reissue application), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 42-74 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Reissue Applications

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 6,007,988 is or was

involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

This application is objected to under 37 CFR 1.172(a) as lacking the written consent of all assignees owning an undivided interest in the patent. The consent of the assignee must be in compliance with 37 CFR 1.172. See MPEP § 1410.01.

A proper assent of the assignee in compliance with 37 CFR 1.172 and 3.73 is required in reply to this Office action.

The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

The amendment filed 12/27/2001 proposes amendments to the specification that do not comply with 37 CFR 1.173(b), which

sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

In the instant case, the proper underlining of added material and square bracketing of the deleted material, was not performed for the amendments to the specification to be entered.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

In the instant case, the application is a reissue of 08/793,408, filed 6/2/97, U.S. Patent No. 6,007,988. This needs to be added to the claim of priority to the PCT application of record, in the first sentence of the application.

Claim Objections

Claims 23-25 are objected to because of the following informalities:

1. Claim 23 recites "encoding zinc finger polypeptides into a vector". This is a grammatically incorrect use of "into". Replacing "into" with -- in -- would be remedial.

2. Claim 32 has two periods at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of "the zinc finger of the Zif 268 polypeptide" renders the claim vague and indefinite because there is no positive antecedent basis for the specific zinc finger and specific Zif 268 polypeptide referred to using "the". Amending

the claim to recite "a zinc finger of a Zif 268 polypeptide" would be remedial.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,013,453. An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir.

1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-41 are generic to all that is recited in claims 1-26 of U.S. Patent No. 6,013,453. That is, claims 1-26 of U.S. Patent No. 6,013,453 fall entirely within the scope of claims 1-41 or, in other words, claims 1-41 are anticipated by claims 1-26 of U.S. Patent No. 6,013,453. Specifically, the DNA library, method of designing a zinc finger, method of producing a zinc finger polypeptide, method of modifying a nucleic acid sequence of interest, and kit of claims 1-26 of '453 are limited to the identical products and methods of claims 1-41 of the instant application, except the products and methods of '453 are further limited to additional limitations such as the zinc finger polypeptide being displayed on a viral particle, the zinc finger polypeptide comprising at least three zinc fingers, and the randomized zinc finger between two or more zinc fingers of defined sequences.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

January 28, 2003